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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,240	05/31/2001	Prasad Pamidi	INL-057	2414
21323	7590	10/07/2004	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 10/07/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,240

Applicant(s)

PAMIDI ET AL.

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 8-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/31/01, 11/21/02.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: IDS 5/9/03, 9/24/03, 6/2/04, 7/14/04.

Art Unit: 1651

DETAILED ACTION

In a response of 7/9/04 to a restriction requirement of 6/16/04, applicants elected Group I claims 1-7 without traverse.

Claims 8-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/9/04.

Claims examined on the merits are 1-7.

On form PTO-1449 of 6/2/04, documents A17 and C17 have been lined through since the documents are previously listed as documents A7 and C13, respectively, by PTO-1449 of 5/31/01. Document B9 listed by PTO-1449 of 6/2/04 and document C18 listed by PTO-1449 of 7/14/04 have been lined through and not considered since copies of the documents have not been received.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the enzyme layer being between and in contact with the inner and outer layers, the outer layer having a thickness of 8-15 microns and being a layer over which sample liquid flows and which controls diffusion of analyte into

Art Unit: 1651

the enzyme layer, and the inner layer being between the enzyme layer and an electrode of the biosensor, being less than one micron thick and having pores small enough to prevent the passage of compounds in a sample liquid larger than hydrogen peroxide so the inner layer

5 functions as an interference rejection membrane, does not reasonably provide enablement for another type of composite membrane having layers as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope
10 with these claims.

It would be speculation and unpredictable as to whether the disclosed results will be obtained when using a composite membrane structured substantially different from the working embodiments described in the specification. The claims must be commensurate in
15 scope with the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

20 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as
25 being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1651

The claims are confusing and unclear as to the relationship of the inner, outer and enzyme layers to each other. It is uncertain where the enzyme layer is positioned relative to the inner and outer layers. Additionally, it is uncertain how one would distinguish the inner and outer layers from each other and know when one layer is outer and the other is inner since there is no biosensor structure recited that will require one layer to be inner and the other to be outer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1651

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansouri et al in view of Heller et al (5,262,305) and Madaras et al and Chen et al (all listed on a form PTO-1449).

The claims are drawn to a composite membrane for a biosensor comprising inner, outer and enzyme layers wherein the enzyme layer is a matrix containing an enzyme, a cross-linking agent and an enzyme stabilizer.

Mansouri et al disclose (Figure 3, page 373) a three-layer composite membrane containing inner, outer and enzyme layers as part of a biosensor.

Heller et al disclose a composite of layers similar to Mansouri et al for use as part of a biosensor wherein a layer containing an enzyme is formed by cross-linking the enzyme in a matrix (col 4, lines 30-37). The enzyme can be lactate oxidase (col 3, line 45) or sarcosine oxidase (col 3, line 51).

Madaras et al disclose a biosensor for creatinine assay. A multienzyme system is used containing creatininase, creatinase and sarcosine oxidase (page 3832, left col, first paragraph). The enzymes are in a layer formed by cross-linking the enzymes with a bifunctional reagent in the presence of an inert protein (page 3836, paragraph bridging the cols).

Chen et al disclose stabilizing oxidases in silica gels with poly(N-vinylimidazole) or poly(ethyleneimine) (abstract, page 4582).

It would have been obvious to prepare the enzyme layer of Mansouri et al by cross-linking with a cross-linking agent to form a

Art Unit: 1651

matrix as suggested by Heller et al and Madaras et al preparing an enzyme layer for a biosensor by using a cross-linking agent to form a matrix containing the enzyme. It would have further been obvious to provide in the matrix a stabilizer taught by Chen et al for
5 stabilizing an oxidase to obtain the expected function of the stabilizer. The enzymes of dependent claims are suggested by Heller et al and Madaras et al for use as enzymes in an enzyme-containing layer of a biosensor.

Conclusion

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,
15 the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

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DMN
10/1/04